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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/674,311 07/01/96 OLOPADE

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EXAMINER

HM12/1123

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ARTHUR, J

ART UNIT

PAPER NUMBER

1655

DATE MAILED:

11/23/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**08/674,311**

Applicant(s)

Olopade

Examiner

Lisa Athur

Group Art Unit  
**1655**



X Responsive to communication(s) filed on Aug 19, 1999

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11, 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133) Extensions of time may be obtained under the provisions of 37 CFR 1.136(a)

## Disposition of Claim

X Claim(s) 39-96 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

Claim(s) \_\_\_\_\_ is/are allowed

X Claim(s) 39-96 is/are rejected

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some\* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received

received in Application No. (Series Code/Serial Number) \_\_\_\_\_

received in this national stage application from the International Bureau (PCT Rule 17.2(a))

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. This application is a continuing prosecution application filed under 37 CFR 1.53(d). Currently claims 39-96 are pending. This action contains new grounds of rejection.

**MAINTAINED REJECTIONS**

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-50,52-57,59,60, 67-76,78,80-83,88-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Kamb et al. (1994).

Kamb et al. Teach isolated polynucleotides containing the tumor suppressor gene MTS1 which maps to 9p21-22. The cosmid that contains MTS1 of Kamb et al. Also contains the human methylthioadenosine phosphorylase gene (MTAP) since these two genes are tightly linked. Thus the cosmid of Kamb et al is an isolated polynucleotide comprising the sequence of SEQ ID no 1 which is a sequence region that encodes a polypeptide comprising the amino acid sequence of SEQ ID NO 2. Necessarily then, the polynucleotide of Kamb et al. Comprises at least 21, 30, 40 or all contiguous bases from nucleotides 122-970 of SEQ ID NO 1 (limitations of claims 40-43). Since the polynucleotide of Kamb et al. Encodes the MTAP gene, it inherently meets the limitations of claims 45 and 46 that the encoded polypeptide promotes melanoma senescence and suppresses glioma cell tumor generation. The cosmid used in Kamb et al. was at least 849 base pairs in length since it contains the CDKN2 which is target than 849 base pairs (limitations of 47-

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49). Kamb et al teaches a method for detecting a nucleic acid comprising a sequence encoding MTAP by hybridization with a probe comprising at least 21 bases of SEQ ID NO 1 because Kamb et al. teaches a Southern blot (Figure 2) was performed using human genomic DNA and a probe which was a cosmid which contains the MTAP gene. Therefore, a nucleic acid containing the MTAP would be detected by hybridization of the cosmid of Kamb et al since the same probe was used by Kamb et al. That was used in the claimed method (claims 78-83).

3. Claims 39-48, 50-60, 67-76, 78-83, 88-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Bolander et al. (1994)

Bolander et al. teach a chromosome fragments, vectors and host cells comprising the MTAP gene and methods of use identical to the claimed invention (see figure 4) because chromosome fragments that comprise the MTAP gene inherently comprises SEQ ID NO 1 encoding a polypeptide of SEQ ID NO 2.

4. Claims 95 and 96 are rejected under 35 U.S.C. 102(b) as being anticipated by Scaletti et al.. Scaletti et al. Disclose methods of distinguishing tumor types by comparing chromosome 9p patterns between tumor types.

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**NEW GROUNDS OF REJECTION**

5. Claims 39-42,45-50-66, 74-75,77-83, 88-94 are rejected under 35 U.S.C. 102(b) as being anticipated by, or in the alternative under 35 U.S.C. 103(a) as being obvious over Nobori et al.

Nobori et al. teach that methylthioadenosine phosphorylase cDNA was isolated and used to probe a human lambda-phage cDNA library and a 2000 base pair fragment was found to contain the 3' end of the MTAP gene (page 753, col. 2, paragraph 3). This sequence was used as a probe for chromosome walking, I.e. in a hybridization detection reaction. The MTAP HindIII fragment was inserted into a vector and transformed into a host cell (page 754). It is noted that Nobori et al. Only discloses a 3' fragment of the human MTAP gene. However, the claims as written read on polynucleotides containing fragments of the MTAP gene as small as 10 bases.

However, the embodiments of the claims limited to a polynucleotide consisting of the MTAP gene would have been prima facie obvious over the teachings of Nobori et al. Because Nobori et al. disclose a highly specific probe for isolating the complete coding sequence for the MTAP gene by teaching a polynucleotide consisting of the 3' end of the MTAP gene. The ordinary artisan would have been highly motivated to obtain the remainder of the MTAP gene because Nobori et al. Taught that they has only isolated a portion of the coding sequence and any ordinary artisan would recognize the need to obtain the remainder of the gene sequence in order to be able the express the full length polypeptide. The ordinary artisan would have had a reasonable expectation for success because Nobori et al. Isolated a probe of 100% sequence

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identity to the gene to be isolated such that very stringent hybridization conditions could be employed in the screening of the human cDNA of Nobori or genomic library to isolated clones containing the full length MTAP sequence. It would have been further obvious to have then expressed the full length MTAP polypeptide encoded by the MTAP nucleic acid obvious over Nobori et al. For the above reasons in order to have achieved the expected benefit of more easily and more quickly producing recombinant MTAP in larger quantities.

6. Claims 84-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nobori et al. or Bolander et al.

Nobori et al. teach that methylthioadenosine phosphorylase cDNA was isolated and used to probe a human lambda-phage cDNA library and a 2000 base pair fragment was found to contain the 3' end of the MTAP gene (page 753, col. 2, paragraph 3). This sequence was used as a probe for chromosome walking, I.e. in a hybridization detection reaction. The MTAP HindIII fragment was inserted into a vector and transformed into a host cell (page 754). It is noted that Nobori et al. Only discloses a 3' fragment of the human MTAP gene. However, the claims as written read on polynucleotides containing fragments of the MTAP gene as small as 10 bases.

Bolander et al. teach a chromosome fragments, vectors and host cells comprising the MTAP gene and methods of use identical to the claimed invention (see figure 4) because chromosome fragments that comprise the MTAP gene inherently comprises SEQ ID NO 1 encoding a polypeptide of SEQ ID NO 2.

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Both Nobori et al. and Bolander et al. teach the association of the 9p21-22 region with cancers due to its frequent deletion in patients with various cancers and teach that this region was suspected to contain a number of tumor suppressor genes.

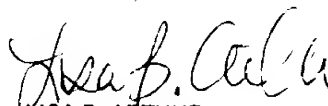
Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the polynucleotides and vectors taught by Nobori et al. Or Bolander et al. With detection reagents in a kit in order to achieve the expected benefit of providing probes to use in a method of screening for deletions of the 9p21-22 region as suggested by Nobori et al. And by Bolander et al. In a convenient form which was easier to distribute and market.

7. No claims are allowable over the prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday-Thursday from 7:00AM to 1:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 3081152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
LISA B. ARTHUR  
PRIMARY EXAMINER  
GROUP 1800-1600

November 22, 1999

Art Unit: 1655

Both Nobori et al. and Bolander et al. teach the association of the 9p21-22 region with cancers due to its frequent deletion in patients with various cancers and teach that this region was suspected to contain a number of tumor suppressor genes.

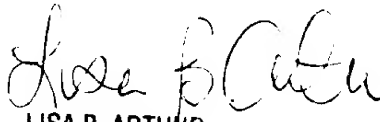
Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have packaged the polynucleotides and vectors taught by Nobori et al. Or Bolander et al. With detection reagents in a kit in order to achieve the expected benefit of providing probes to use in a method of screening for deletions of the 9p21-22 region as suggested by Nobori et al. And by Bolander et al. In a convenient form which was easier to distribute and market.

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November 22, 1999